Baywater, Inc.
15425 Smoland Lane
Bainbridge Island, WA 98110
206-842-0894

April 14, 1999

William K. Hubbard
Dockets Management Branch (HFA-305)
FDA
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re: **Federal Register Request for Information: Performance Standard for Vibrio vulnificus Docket Number 98P-0504 - Volume 64, Number 13, Page 3300-3301**

Dear Mr. Hubbard:

I am writing in response to the request for information with regards to a petition submitted by the Center for Science in the Public Interest (CSPI). I understand that there are eight points of interest raised by the petition. My comments will respond generally to these points. In general, I am very concerned about the potential for policy to be promulgated at the request of a private interest group (the CSPI), as opposed to an open process using science, a collaborative approach and the Interstate Shellfish Sanitation Conference (ISSC) as the forum. This is the purpose of this regulatory body, and I am very concerned that a private interest group is attempting to subvert the process by submitting a petition directly to the FDA.

As a shellfish grower and research scientist working in Washington State, I am alarmed at the step the FDA is taking with respect to its policies generated by the FDA for controlling *Vibrio parahaemolyticus* (P.v.) levels in Pacific oysters grown in the State of Washington. As you may know, the oyster industry here is very closely regulated by state and Federal law with respect to human health issues for any number of possible problem areas. In addition, as growers we have a very high level of cooperation with our grower's association, the Pacific Coast Oyster Grower's Assoc.

With respect to P.v., we are currently operating under an interim control plan which has been highly effective, by anyone's estimate with very few illnesses reported in 1998. While our goal is to have nobody get sick as a result of ingesting raw oysters, we feel we have been extremely responsible with respect to this issue. Of course, as we gain further knowledge of critical P.v. levels in nature, and the levels necessary to induce illness, we will be able to respond quickly and effectively to a performance standard.

The bottom line is that as a grower of very high value oysters grown for white table cloth restaurants, I am critically concerned with quality. Please don't allow the CSPI to destroy the ability for consumers to continue to enjoy our product, and others like it. The Ameripure process is completely unacceptable to me as a means for treating the

98P-0504

C61

problem of V.p. in Pacific oysters. I will not grow live oysters to be sold dead on the halfshell.

What needs to occur is for the FDA to allow the ISSC to continue to develop the procedures and safeguards necessary to protect the consumer, as it has in the past.

What also needs to occur is a recognition by the FDA that critical biological factors separate oyster growing areas on a regional basis. The Pacific northwest region does not have a significant problem with *V. fulnificus*, whereas other regions of the country do (e.g. the Gulf region). If regional differences exist in growing conditions, as well as in the regulatory framework(both statutory and voluntary), then perhaps there needs to be regional differences in how this problem is dealt with from the perspective of public health policy development. In either case, I urge you to use the process which has worked in the past comprising science based research followed by collaborative development of policies by the ISSC.

I also urge the FDA to fund the necessary research to determine safe levels of V.p. in shellfish in order to establish a performance standard, as this will go a very long ways to resolve this significant problem we all face.
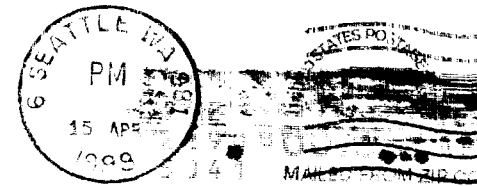
Thank you very much.

Sincerely,

Jonathan P. Davis, Ph.D.

Baywater, Inc.
15425 Smoland Lane
Bainbridge Island, WA 98110

William K. Hubbard
Dockets Management Branch (HFA-305)
FDA
5630 Fishers Lane, Room 1061
Rockville, MD 20852

20857+0001